DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 24, 2014

Crosstex International
Mr. Michael G. Nolan
Research and Development Coordinator
6789 West Henrietta Road
Rush, NY 14543

Re: K140566
Trade/Device Name: SPSmedical VH2O2 Indicators
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: October 21, 2014
Received: October 22, 2014

Dear Mr. Nolan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) NUMBER (IF KNOWN): K140566

DEVICE NAME: SPSmedical VH_2O_2 Indicators

INDICATIONS FOR USE:

A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO™ 1, V-PRO™ 1 Plus (Lumen & Non-lumen), V-PRO® maX (Flexible, Lumen & Non-lumen) and Sterilucent™ PSD-85 (Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.

CATALOG NUMBER	PRODUCT NAME
GPS-250R	Indicator Strip
GPS-250Y	Indicator Strip
GPL-2000R	Indicator Label
GPL-2000Y	Indicator Label
HT-048	Indicator Tape
HT-036	Indicator Tape
5093	Indicator Card

Prescription Use:_____ and/or Over-the-Counter Use: X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

SUBMITTER INFORMATION

SPSmedical Supply Corp.		Contact:	Michael G. Nolan
a division of Crosstex International			Research and Development Coordinator
6789 West Henrietta Road		Phone:	(800) 722-1529
Rush, NY 14543 U.S.A.		Fax:	(585) 359-0167
Date of Summary:	November 24, 2014		

DEVICE NAME AND CLASSIFICATION

Device Trade Name:	SPSmedical VH_2O_2 Indicators
Common Name:	Vaporized Hydrogen Peroxide Chemical Indicators
Classification Name:	Physical/chemical sterilization process indicator 21 CFR § 880.2800(b)
Review Panel:	General Hospital
Product Code:	JOJ
Device Class:	II

PREDICATE DEVICE:

The SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators cleared under K110152.

DEVICE DESCRIPTION:

The SPSmedical VH_2O_2 Indicators are single use process indicators which are cleared for use in verifying exposure to all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX, NX, STERIS® V-Pro 1, V-Pro 1 Plus, and V-Pro maX Testing has been performed which validated the SPSmedical VH_2O_2 Indicators for use in the Sterilucent PSD-85 Sterilizer.

Indicators will identify if an item has seen H_2O_2 during the Sterilucent PSD-85 sterilization processes by changing to a Blue signal color. They provide a visual indication to help distinguish between processed and unprocessed items.

INTENDED USE:

The SPSmedical VH_2O_2 Indicators are intended for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX, NX, STERIS® V-Pro 1, V-Pro 1 Plus, V-Pro maX and Sterilucent PSD-85 sterilization processes. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items. Indicators change to a signal color of Blue after exposure to vapor hydrogen peroxide.

TECHNICAL CHARACTERISTICS:

The chemical indicator ink utilized on the SPSmedical VH2O2 Indicators has been formulated to meet the performance requirements ANSI/AAMI/ISO 11140-1 for Process Indicators. When applied to different synthetic substrates the Indicators are indicated for use as internal strips, external cards, labels or tape. Which all function as process indicators.

BIOCOMPATIBILITY

The information provided here is identical between to K110152, and no modifications have been made to the proposed device when compared with the K110152 device. SPSmedical VH_2O_2 Chemical Indicators are manufactured using nontoxic inks and substrates that will not alter the chemical composition of the products being sterilized and are safe for human contact. Indicators can be disposed in general waste receptacles as no Material Safety Data Sheet (MSDS) is required.

510(k) Summary

STORAGE CONDITIONS:

Store in a cool, dry place (15-30°C).

NON-CLINICAL TESTING:

Verification and validation tests were performed as a result of a Failure Mode and Effects Analysis (FMEA).

Various testing, including testing to ANSI/AAMI/ISO 11140-1:2005(R)2010 requirements for indicators being run in vaporized hydrogen peroxide sterilization processes was performed. Testing also included simulated use in the Sterilucent PSD-85 sterilization processes. Multiple lots of indicators with various levels of shelf life were included in testing.

All lots of SPSmedical VH_2O_2 Indicators gave acceptable results for all tests performed.

COMPONENTS:

The components of the SPSmedical VH2O2 Indicators are all previously approved materials for the Vaporized Hydrogen Peroxide Sterilization Process. Substrates and manufacturing processes used for the Subject device are identical to the substrates and manufacturing processes used in K110152. Indicators are composed of commercially existing materials of synthetic paper or label stock (e.g. Tyvek®, polypropylene, polystyrene etc…). The indicator ink is a nontoxic sterilization indicator ink that changes from an initial color of pink or yellow to a blue signal color when exposed to the Hydrogen Peroxide Sterilization Process.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

SPSmedical Supply Corp. has identified the SPSmedical VH_2O_2 Indicators cleared under K110152 to show equivalence to the proposed SPSmedical VH_2O_2 Indicators. Both the predicate and proposed chemical indicators are the same indicators made with the same indicator ink, substrates and manufacturing process. There is no difference between the predicate and proposed VH_2O_2 indicators. Therefore, the proposed SPSmedical VH_2O_2 Indicators are substantially equivalent to the predicate in terms of their use and functional characteristics in VH_2O_2 sterilization processes.

PREDICATE I.D.

Trade Name:	SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators	
Model No.:	GPS-250R	Indicator Strip
	GPS-250Y	Indicator Strip
	GPL-2000R	Indicator Label
	GPL-2000Y	Indicator Label
	HT-048	Indicator Tape
	HT-036	Indicator Tape
	5093	Indicator Card
Submitter/holder:	SPSmedical Supply Corp. *a division of Crosstex Internationa*l 6789 West Henrietta Road Rush, NY 14543 U.S.A. Phone: (585) 359-0130 Fax: (585) 359-0167	
510(k) No.:	K110152	

510(k) Summary

COMPARISON OF INDICATIONS FOR USE (IFU):

Predicate IFU—The SPSmedical H2O2 Chemical Indicator are indicated for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX, NX and STERIS® V-Pro1, V-Pro 1 Plus and V-Pro maX sterilizers. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items. Indicators change to a signal color of Blue after exposure to vapor hydrogen peroxide.

Subject IFU—A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO™ 1, V-PRO™ 1 Plus (Lumen & Non-lumen), V-PRO® maX (Flexible, Lumen & Non-lumen) and Sterilucent™ PSD-85 (Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.

Discussion—The Predicate and Subject Device are the same device in materials and manufacturing, but the indications for use are slightly different. With the Subject IFU we have added the sterilization cycle names which they were always cleared for, but not clearly identified. The addition of a label claim and the grounds of this 510(k) submission the PSD-85 (Lumen & Non-lumen) cycles have been added.

DESIGN DIFFERENCES PREDICATE VS. SUBJECT DEVICE:

There are no changes in design from the Predicate to the Subject Device. Only an additional Indication for Use as been added which is the Sterilucent PSD-85 (Lumen and Non-lumen) cycle.

FUNCTIONAL CHARACTERISTICS

The SPSmedical VH_2O_2 Indicators are designed to monitor sterilization cycles in low temperature VH_2O_2 type sterilizers. They are a reliable tool used for the monitoring of VH_2O_2 sterilization processes and provide a visual indication that hydrogen peroxide (H_2O_2), an essential ingredient in the vaporized hydrogen peroxide sterilization process has been introduced into the sterilizer's chamber. Indicators will identify if an item has seen H_2O_2 during the sterilization process. Indicators change from an initial color of Yellow or Pink to a final signal color of Blue.

DISCUSSION

SPSmedical is claiming substantial equivalence for its proposed SPSmedical VH_2O_2 Indicators to the current SPSmedical H_2O_2 Indicators based on test data taken during comparison studies. We have demonstrated with testing that the SPSmedical VH_2O_2 Indicators perform consistently with results which indicate exposure to the VH_2O_2 sterilization process.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS

The proposed SPSmedical VH_2O_2 Indicators have the same intended use and characteristics as the current SPSmedical H_2O_2 Indicators. Both provide a visual indication that the indicator has been exposed to the H_2O_2 sterilization process. The SPSmedical products are comprised of synthetic materials and are printed with an indicator ink which provides a signal color after exposure to the H_2O_2 sterilization process. The performance of the SPSmedical VH_2O_2 Indicators have been validated through testing directed by SPSmedical.

SPSmedical believes that the SPSmedical VH_2O_2 Indicators are substantially equivalent to the predicate device because they are the same device without any modifications. Both the current and proposed indicators have the same intended use, technical characteristics and performance. Because the ability to perform its intended function has been shown through validated testing and the SPSmedical line of VH_2O_2 Indicators raises no issues related to safety or effectiveness. Based on

the nonclinical tests performed the subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device, Class II (21 CFR 880.2800(b)), product code JOJ. See Table 1 for a substantial equivalence comparison.

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

ELEMENT	PROPOSED DEVICE	PREDICATE (K110152)
Intended Use	Process Indicator	Process Indicator
Indications for Use	A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO™ 1, V-PRO™ 1 Plus (Lumen & Non-lumen), V-PRO® maX (Flexible, Lumen & Non-lumen) and Sterilucent™ PSD-85 (Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.	The SPSmedical H2O2 Chemical Indicator are indicated for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX, NX and STERIS® V-Pro1, V-Pro 1 Plus and V-Pro maX sterilizers. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items. Indicators change to a signal color of Blue after exposure to vapor hydrogen peroxide.
Device Design	Strip, Label, Tape, Card etc.	Strip, Label, Tape, Card etc.
Endpoint Color	Signal Color of Blue	Signal Color of Blue
Indicator Agent	H_2O_2 Indicator Ink	H_2O_2 Indicator Ink
Sterilization Method	Vaporized Hydrogen Peroxide	Vaporized Hydrogen Peroxide
Device Materials	Same (Synthetic Substrate)	Same (Synthetic Substrate)
Performance under ISO 11140-1 Complete reaction cycle	Equivalent	Equivalent
Performance under ISO 11140-1 Incomplete reaction cycle	Equivalent	Equivalent
Biocompatibility	Equivalent	Equivalent
Non-clinical Performance-Sterilucent PSD-85 (Lumen & Non-Lumen cycles)	Complete Cycle Turns Blue with yellow/green intermediate (Same)	Complete Cycle Turns Blue with yellow/green intermediate (Same)
Same Shelf-life	Up to 2 years	Up to 2 years

510(k) Summary

CONCLUSION:

The subject device SPSmedical VH_2O_2 chemical indicators have the same intended use and characteristics as the predicate SPSmedical H_2O_2 chemical indicators. Both provide a visual indication that the indicator has been exposed to the PSD-85 sterilization process.

SPSmedical believes that the SPSmedical VH_2O_2 chemical indicators are substantially equivalent to the predicate device because they are the same device without any modifications. Both the subject and predicate indicators have the same intended use, technical characteristics and performance. Based on the non-clinical performance testing data the subject device has proven to be as safe and effective as the predicate device when monitoring the PSD-85 sterilization processes and can be safely marketed in the United States.